REMARKS

Upon entry of the present amendment, claims 1 – 4, 6, 7, 10 – 19, 21 – 26, and 29 – 31 are pending. Claims 5, 8, 9, 20, 27, 28 and 32 – 37 have been cancelled. Claims 1, 30 and 31 have been amended to now recite a composition that comprises "a calcium salt in a concentration of at least 200 mM, such that the composition is hypertonic" wherein the "composition" retains at least 50% of its "initial" biological activity. Basis for this amendment can be found in the Specification as originally filed, and in particular, at Paragraphs [0042], [0050] and [0069] of Published U.S. Application No. 20040037893. Claim 17 has been amended to correct a typographical error. The present amendment adds no new matter.

REJECTION UNDER 35 U.S.C. §112, 2ND

The Examiner has rejected claims 1-19, 21-26, and 29-31 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner has stated that it is unclear what is meant by the recitation "said factor VII polypeptide retains at least 50% of its biological activity".

Applicants have amended claims 1, 30 and 31 to now recite "wherein said *composition* retains at least 50% of its *initial* biological activity. Basis for this amendment can be found in the Specification as originally filed, and in particular, at Paragraphs [0050] of Published U.S. Application No. 20040037893. Accordingly, in light of the present amendment, Applicants request reconsideration and withdrawal of the present rejection.

THE 35 U.S.C. §102(B) REJECTIONS

The Examiner has rejected claims 1-7, 9-16, 21-23, 25-26 and 29-31 under 35 U.S.C. 102(b) as being anticipated by The Medicine Catalogue ("**The Medicine Catalogue**").

Applicants disagree. The Examiner has alleged that **The Medicine Catalogue** discloses a composition comprising recombinant Factor VII, 105 mg of $CaCl_2$, 1.3 mg glycylglycine, 30 mg mannitol, 3.0 mg sodium chloride and 0.1 mg polysorbate, wherein the composition has a pH of 5.4 to 6.0. However, a review of **The Medicine Catalogue** shows that it does not, as stated by the Examiner, disclose a composition with 105 mg $CacCl_2$, but instead discloses **1.5 mg $CaCl_2$** (both the

English and Danish translation text disclose 1.5 mg). Moreover, the listed amounts in Section 7 of **The Medicine Catalogue** are *mg per ml* – consequently, the Examiner is incorrect in referring to "concentrations, respectively for 8, 4, and 2 mls" (page 4, lines 1-8 of the May 31, 2007 Office Action). The amounts (mg) being per mL is clearly stated in The Medicine Catalogue in the Section entitled "Dispensed in the form of". Thus, the concentrations of $CaCl_2$ and NaCl are, at most, approximately 10 mM $CaCl_2$ dihydrate (13 mM CaCl2 in case of anhydrous) and 50 mM (NaCl). They are not several hundred, as characterized by the Examiner. Thus, Applicants assert that the present invention is not anticipated by **The Medicine Catalogue**.

The Examiner has also rejected claims 1-7, 9-19,21-26, 29-31 under 35 U.S.C. 102(b) as being anticipated by Johannessen et al (WO 01/82943; "**Johannessen**"). Specifically, the Examiner has alleged that **Johannessen** discloses Factor VII for the manufacture of a medicament, where the medicament can be a stable, aqueous solution comprising Factor VII, a salt in order to give an isotonic solution in an amount more than 1.0 mg/ml…calcium chloride in an amount of more than 0.15mg/ml.

In order to more clearly define the present invention, Applicants have amended claims 1, 30 and 31 to now recite a composition that comprises "a calcium salt in a concentration of at least 200 mM, such that the composition is *hypertonic*". Basis for this amendment can be found in the Specification as originally filed, and in particular, at Paragraphs [0050] and [0069] of Published U.S. Application No. 20040037893. Accordingly, in light of the present amendment, Applicants request reconsideration and withdrawal of the present rejection.

THE 35 U.S.C. §103(A) REJECTION

The Examiner has rejected claim 8 under 35 U.S.C. 103(a) as being unpatentable over **The Medicine Catalogue** as applied to claims 1-7, 9-16, 21-23, 25-26, and 29-31 above, and further in view of Miekka et al (WO 97/19687; "**Miekka**").

Applicants have cancelled claim 8. Accordingly, Applicants believe that the present rejection is now moot.

THE NON-STATUTORY DOUBLE PATENTING REJECTION

The Examiner has provisionally rejected claims 1, 7, 8, 10-12, 14-15, 17-19 and 24 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1-7, 11, 12, and 16-19 of copending U.S. Patent Application No. 10/602340.

Upon notification of allowable subject matter, Applicants will review the need for a terminal disclaimer.

CONCLUSION

In view of the above, it is respectfully submitted that the application is now in condition for allowance and issue. The Commissioner is hereby authorized to charge any fees in connection with this application and to credit any overpayments to Deposit Account No. 14-1447.

Respectfully submitted,

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